

**U.S. Patent Application of:**

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**for**

**Title: Surgical Stapler with Removable Staple Cartridge**

## Cross-Reference to Related Applications

"This application is entitled to the benefit of Provisional Patent Application Ser.#60-406574, filed August 29, 2002."

## Field of the Invention

This invention relates to a surgical stapler for implanting staples into the skin and/or tissue for wound closure after a traumatic injury or a purposeful incision in a surgical procedure.

## Background of the Invention

It has become a preferred procedure to use staples for wound closure rather than thread or filament sutures. Surgeons choose staples because of the speed with which an incision can be closed as compared with the time consuming placing and tying of thread or filament sutures.

Many surgical staplers have been designed with various features. See, for example, U.S. Pat. Nos. 6,601,748, 4,014,492, 4,109,844, 4,179,057, 4,202,480, 4,256,251, 4,375,866, 4,407,286, 4,489,875, 4,527,725, and 4,662,555. The above patents describe staplers using preformed staples without a forming anvil, staplers having a stationary forming anvil, and staplers having a movable or retractable forming anvil as well as a wide variety of feeding mechanisms to deliver each staple to the delivery point where the staple is formed during implantation into the skin and/or tissue.

Although the use of surgical staplers are wide spread, still in most cost sensitive markets, such as veterinary surgery, thread or filament sutures are still most commonly used. In an effort to decrease the cost of using surgical staplers and allow staplers to be more cost efficient, one approach is to reduce the disposable portion of the stapler into a separate cartridge assembly to be used in conjunction with a reusable handle assembly. This decoupling of the cartridge and handle assemblies in turn creates other challenges related to the retention and alignment of the cartridge inside the handle. The present invention provides a novel structure to prevent this problem as explained more fully hereinafter.

## Brief Summary of the Invention

The surgical stapler with a removable staple cartridge of the present invention is formed of a combination of a handle assembly and a removable staple cartridge assembly, which are adapted to fit together so that an empty cartridge may be removed and replaced with a cartridge full of surgical staples. A partial closing of the handle assembly engages the forming tool into a beveled opening in the front of the removable staple cartridge locking the cartridge in the correct position in the handle so that a staple may be formed. The actuating trigger is then held in a latched position through a spring-loaded latch, which holds the handle assembly in a ready to use position but prevents the accidental disengagement of the removable staple cartridge assembly from the handle. The continued closing action of the handle assembly displaces the forming tool to form a staple into place. As the surgical staple which is fed between the form tool and the anvil portion of the removable staple cartridge rail as the leading one of a plurality of surgical staples pre-loaded into the removable staple cartridge assembly on a cartridge rail is moved toward and between the form tool and the anvil by the action of a clip pusher which is biased toward the form tool and anvil until inserted into the skin.

The specific advantages of the present surgical stapler will be described and explained more fully in the following detailed description.

## Brief Description of the Drawings

The surgical stapler of this invention will be described in more detail with reference to the accompanying drawings, which show one illustrative specific embodiment of the invention.

FIG. 1 is a perspective view of the surgical stapler handle assembly, with the removable staple cartridge loaded into the handle and the trigger in the latched position.

FIG. 2 is a perspective view of the surgical stapler assembly, with the actuating trigger in the open position and the removable staple cartridge removed.

FIG. 3 is a perspective view of the surgical stapler assembly with the actuating trigger in the full closed position.

FIG. 4 is an enlarged partial view of the surgical stapler assembly in its full closed position and showing a staple completely formed.

FIG. 5 is a detailed perspective view of the surgical stapler assembly in its fully open position with a partial view of the handle showing the actuating trigger release mechanism.

FIG. 6 is a perspective view of the actuating trigger release mechanism showing all its comprising components.

FIG. 7 is a section view of the latch assembly showing the position of the actuating trigger inside the handle assembly as the removable staple cartridge is locked in the applier handle.

FIG. 8 is a side cutaway view of the surgical stapler assembly in the full closed position showing the components that comprise the removable staple cartridge assembly and the actuating trigger.

FIG. 9 is a cutaway side view of the stapler assembly showing the interaction of the actuating trigger and the return leaf spring.

FIG. 10 is a perspective view of the removable staple cartridge assembly showing all its comprising elements.

FIG. 11 is a perspective view of the removable staple cartridge assembly showing the large holes for passive visual indication of the remaining staples.

FIG. 12 is a perspective view of the removable staple cartridge assembly as shown in Fig. 7, but with the cartridge cover removed to reveal the inner components of the cartridge.

FIG. 13 is a section view of the removable staple cartridge assembly through a longitudinal plane showing all its components.

FIG. 14 is a cross section across the width of the removable cartridge assembly showing the location of the pusher in relation to the rest of the assembly.

FIG. 15 is a cross section view of the removable staple cartridge assembly through the centerline of the staple body. This shows the position of the staple at an angle inside the cartridge assembly.

FIG. 16 is an enlarged cutaway perspective view of the surgical stapler assembly showing the interaction of the forming tool, actuating trigger and removable staple cartridge assembly in the ready-to-use position.

FIG. 17 is an enlarged cutaway perspective view of the surgical stapler assembly showing the interaction of the forming tool, actuating trigger and removable staple cartridge assembly in the full position with a surgical staple fully formed.

FIG. 18 is a section view through the width of the surgical stapler assembly in the ready-to-use position and across the forming tool showing the relative location of the forming tool with respect to the staple in the removable staple cartridge assembly.

FIG. 19 is a perspective view of the removable staple cartridge assembly end cap.

FIG. 20 is an enlarged longitudinal cross section view showing in detail the rack and pinion interaction among the gear teeth of the actuating trigger and the forming tool.

FIG. 21 is a cutaway view of the stapler assembly showing the actuating trigger in the fully open position and a removable staple cartridge being loaded.

FIG. 22 is a section view through the width of the stapler assembly in the fully closed position and across the forming tool showing the relative location of the forming tool after a staple has been fully formed.

## Detailed Description of the Drawings

With reference to the accompanying drawings, the same parts are identified by the same reference numeral in all figures of the drawings.

In FIG. 1, a specific embodiment of the surgical stapler of the present invention, indicated generally by reference numeral 32, is shown in an attitude of use after having placed staples 38 to close a wound for an incision 31. The surgical stapler 32 includes a handle assembly 33, an actuating trigger 34, and a removable staple cartridge 35 which are detachable from one another.

FIG. 2 shows the stapler assembly 32 with the actuating trigger 34 in its full open position with respect to handle assembly 33 and a removable staple cartridge 35 ejected from the stapler. The handle assembly 33 and actuating trigger 34 are connected by a pivot screw 37, which allows trigger 34 to rotate about the center of the screw. Attached to the back end of the actuating trigger 34, there is a release mechanism 36. This release mechanism allows the engagement and disengagement of trigger 34 to handle 33.

Trigger 34 is designed to operate in three main positions, fully open (FIG. 2), ready-to-use position (FIG. 1) and fully closed (FIG. 3). When trigger 34 is pulled to the fully open position removable staple cartridge 35 is disengaged from forming tool 46 and can be removed and replaced by a new one. The detailed description of how this operation takes place will be described in detail in later paragraphs. When stapler assembly 32 is in the ready-to-use position (FIG. 1), the snap feature 42 is engaged on lip 44 located in the inside wall of the stapler handle 33 as shown (FIG. 5). The snap features located in the release mechanism 42 prevent trigger 34 from fully opening during the normal operation of the device. When the release buttons 43 are pressed the snap feature 42 clears the housing lip 44 allowing trigger 34 to fully open therefore permitting the discharge of the empty cartridge 35.

FIG. 6 shows in detail the various components that form the release mechanism 36. The assembly is composed of a leaf spring 40 and two latches 41. Latches 41 are made out of a resilient plastic material, which can be heat staked or ultrasonic welded to the leaf spring 40.

During the closing motion of the trigger 34, the snap features 42 in the latches 41 are forced against the inside surface of stapler handle 33. The spring action of leaf spring 40 allows the insertion of snap features 42 into the retention lip 44. While the closing motion of trigger 34 is in no way restricted by the contact of snap features 42 against the inside wall of handle 33 it is obvious that the motion in the opposite direction would be prevented by the retention lip 44 (FIG. 7).

Full closure of trigger 34 is reached when, as shown in (FIG. 8), the top surface of trigger 34 hits the inside top of handle 33. The return movement of the trigger 34 to the ready-to-use position is activated by the extension of leaf spring 45 as shown in (FIG. 9).

FIG. 10, 11, 12, and 13 show in detail the various components of the removable staple cartridge assembly 35. Removable staple cartridge assembly 35 includes a cartridge housing 47, an end cap 52, a rail 53, staples 38, a pusher 50, and a coil spring 60. The rail 53 consists of a high strength steel plate formed to provide the necessary surfaces for the staples 38 to ride on. At the front of rail 53 there is a formed tip or anvil 55 that provides support to the staple 38 during its forming operation. In addition, rail 53 has 4 large holes 63 (FIG. 11) that provide the user with a visual indication of the number of staples 38 remaining in the removable staple cartridge 35.

The cartridge housing 47 is made out of a resilient plastic material and is assembled to rail 53 by heat staking or ultrasonic welding the cartridge pins 56 to the holes 61 located on the side surfaces of rail 53. At the back end of the cartridge housing 47 there is a pair of cantilever snaps 54 that provide the means of engagement to the stapler handle 33 when the removable staple cartridge 35 is loaded into the stapler assembly 32. At the front end of cartridge housing 47 there is a tower 64 with an opening 65 (FIG. 10) that provides access to forming tool 46 once trigger 34 is rotated to the ready-to-use position and forces forming tool 46 into the window 65. As it will be explained in detail in the following paragraphs, this interaction is a very important since it is what allows the perfect alignment between forming tool 46 and a staple 38 just before being formed.

Once the cartridge housing 47 and rail 53 are assembled they formed a cavity where a quantity of thirty-eight staples 38 are loaded (FIG. 12, 13, 14, 15). When all the staples 38 are loaded they lay between rail 53 and the cartridge housing 47 at such an angle that when the stapler assembly 32 is in use the tips of staples 38 face perpendicular to the incision to be closed. FIG. 15 shows a cross section through removable staple cartridge 35 and through the centerline of staple 38. As shown, staple 38 is constrained by the inside walls of cartridge housing 47 and the tips ride on the surfaces 57 and 58 of rail 53. Pusher 50 provides a constant force against staples 38 via the compression force exerted by coil spring 60. Spring 60 is retained inside a cylindrical cavity 50 inside the cartridge housing 47. This allows spring 60 to extend only in the longitudinal direction of the removable staple cartridge 35.

Once staple 38 is formed and pulled out of cartridge assembly 35 a new one is immediately located in place by the force exerted by spring 60 and pusher 50. When the first staple 38 of the stack is in place and ready to be formed, this one is retained at the front by two built in lips 62 into the cartridge housing 47 as shown in FIG. 10, 11, 16 and 17). The mid-section of staple 38 is restrained by the anvil 55 and its side legs by the inside surfaces of cartridge housing 47 (FIG. 18). The end cap 52 is also made out of plastic and is assembled to the rail via two snaps 66 located at the bottom of end cap 52. The end cap surfaces 67 shown in FIG. 19 slide under the bottom surface of cartridge housing 47.

FIG. 16, 18 and 20 show the relative positions of the components that form the staple feeding mechanism when the stapler 32 is in the ready-to-use position. In this arrangement, the removable staple cartridge 35 is engaged in the handle 33 via the snaps 54 on the removable staple cartridge housing 47. This prevents the removable cartridge 35 from accidentally discharging from the stapler assembly 32 when trigger 34 is in the fully open position. In addition, the removable staple cartridge 35 is secured side to side by the walls of the stapler handle 33 (FIG. 16,18).

The removable staple cartridge 35 is locked in position when the forming tool 46 is pushed down during the rotation of trigger 34 to the ready-to-use position (FIG. 9,16,18, 20). When a new removable staple cartridge 35 is inserted into the stapler handle 33 and trigger 34 is brought up from its fully open position (FIG. 5, 21) to the ready-to-use position several actions take place. First, trigger 34 via its gear teeth 48 forces the forming tool 46 to slide between the guides 49 inside the walls of the stapler handle 33. Second, the snap features 42 of the release assembly 36 snap into the housing lip 44. Third, the forming tool 46 engages into the window 65 (FIG. 16, 20) of the removable staple cartridge 35 and aligns and locks the removable staple cartridge 35 into position (FIG. 18). At this point, the forming tool 46 is completely aligned to the centerline of the staple 38 and ready to be formed. This is very important to prevent jamming of the stapler during closing of the wound. The rack and pinion action between the teeth 48 of trigger 34 and the teeth 51 of the forming tool 46 guarantees a very precise and smooth motion of the forming tool 46 inside the housing guides 49 of the stapler housing 33 and window 65 of the cartridge housing 35. When trigger 34 is actuated to the full closed position, its gear teeth 48 force the forming tool 46 downward to make contact with the top section of the staple 38. At this point the extension legs 69 of the forming tool 46 start the deformation of the staple legs. The mid section of the staple 38 is resisted by the anvil 55. This process continues until the edge 68 of the forming tool 46 has completely reached the bottom and presses against the top section of the staple 26 (FIG. 15). When trigger 34 is in its full closed position and the forming tool has completely finished its downward travel, the side legs of the staple 38 then clear the lips 62 of the cartridge housing 47 (FIG. 3, 8,17 ,22) and the staple 38 is free to clear the removable staple cartridge 35 and being implanted into the wound. As soon as the staple 38 is out, the leaf spring 45 pushes trigger 34 back to the ready-to-use position and the cartridge assembly pusher 50 and spring 56 push a new staple 38 into position. This process is repeated until all 38 staples 38 are utilized.

Although, the descriptions above contain many specificities, these should not be construed as limiting the scope of the invention, but merely providing illustrations.

Thus, the scope of the invention should be determined by the appended claims and their legal equivalents, rather than by the examples given.